Application No.: 09/688,672

Page 5





- 1. (as filed) A pharmaceutical composition comprising an M5081 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, and an Mo2 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex.
- 2. (as filed) The composition of claim 1, wherein the antigens are covalently linked, thereby forming a fusion polypeptide.
- 3. (as filed) The composition of claim 2, wherein the fusion polypeptide has the amino acid sequence of TbF14.
- 4. (as filed) A pharmaceutical composition comprising a TbRa3 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, a 38kD antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, a Tb38-1 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, and a FL TbH4 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex.
- 5. (as filed) The composition of claim 4, wherein the antigens are covalently linked, thereby forming a fusion polypeptide.
- 6. (as filed) The composition of claim 5, wherein the fusion polypeptide has the amino acid sequence of TbF15.

Application No.: 09/688,672

Page 6

7. (as filed) A pharmaceutical composition comprising an HTCC#1 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, and a TbH9 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex.

- 8. (as filed) The composition of claim 7, wherein the antigens are covalently linked, thereby forming a fusion polypeptide.
- 9. (as filed) The composition of claim 7, comprising a full-length HTCC#1 antigen from a *Mycobacterium* species of the tuberculosis complex, and a full-length TbH9 antigen from a *Mycobacterium* species of the tuberculosis complex.
- 10. (as filed) The composition of claim 9, wherein the antigens are covalently linked, thereby forming a fusion polypeptide.
- 11. (as filed) The composition of claim 10, wherein the fusion polypeptide has the amino acid sequence of HTCC#1(FL)-TbH9(FL).
- 12. (as filed) The composition of claim 7, comprising a polypeptide comprising amino acids 184-392 of an HTCC#1 antigen from a *Mycobacterium* species of the tuberculosis complex, a TbH9 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, and a polypeptide comprising amino acids 1-129 of an HTCC#1 antigen from a *Mycobacterium* species of the tuberculosis complex.
- 13. (as filed) The composition of claim 12, wherein the antigens are covalently linked, thereby forming a fusion polypeptide.

**PATENT** 

Application No.: 09/688,672

Page 7

- 14. (as filed) The composition of claim 13, wherein the fusion polypeptide has the amino acid sequence of HTCC#1(184-392)/TbH9/HTCC#1(1-129).
- 15. (as filed) A pharmaceutical composition comprising a TbRa12 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, and an HTCC#1 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex.
- 16. (as filed) The composition of claim 15, wherein the antigens are covalently linked, thereby forming a fusion polypeptide.
- 17. (as filed) The composition of claim 16, wherein the fusion polypeptide has the amino acid sequence of TbRa12-HTCC#1.
- 18. (as filed) A pharmaceutical composition comprising at least two heterologous antigens from a *Mycobacterium* species of the tuberculosis complex or an immunogenic fragment thereof, wherein the antigen or immunogenic fragment thereof is selected from the group consisting of MTb81, Mo2, TbRa3, 38kD, Tb38-1 (MTb11), FL TbH4, HTCC#1 (Mtb40), TbH9, MTCC#2 (Mtb41), DPEP, DPPD, TbRa35, TbRa12, MTb59, MTb82, Erd14 (Mtb16), FL TbRa35 (Mtb32A), DPV (Mtb8.4), MSL (Mtb9.8), MTI (Mtb9.9A, also known as MTI-A), ESAT-6, α-crystalline, and 85 complex.
- 19. (as filed) The composition of claim 18, wherein the antigens are covalently linked, thereby forming a fusion polypeptide.
- 20. (as filed) The composition of claim 1, 4, 7, 15, or 18, wherein the antigens are covalently linked via a chemical linker.

Application No.: 09/688,672

Page 8

- 21. (as filed) The composition of claim 20, wherein the chemical linker is an amino acid linker.
- 22. (as filed) The composition of claim 1, 4, 7, 15, or 18, further comprising at least one additional antigen from a *Mycobacterium* species of the tuberculosis complex, wherein the antigen is selected from the group consisting of MTb81, Mo2, TbRa3, 38kD, Tb38-1 (MTb11), FL TbH4, HTCC#1 (Mtb40), TbH9, MTCC#2 (Mtb41), DPEP, DPPD, TbRa35, TbRa12, MTb59, MTb82, Erd14 (Mtb16), FL TbRa35 (Mtb32A), DPV (Mtb8.4), MSL (Mtb9.8), MTI (Mtb9.9A, also known as MTI-A), ESAT-6, α-crystalline, and 85 complex, or an immunogenic fragment thereof.
- 23. (as filed) The composition of claim 1, 4, 7, 15, or 18, further comprising an adjuvant.
- 24. (as filed) The composition of claim 23, wherein the adjuvant comprises QS21 and MPL.
- 25. (once amended) The composition of claim 23, wherein the adjuvant is selected from the group consisting of pVac, BCG, lipid A, Freund's complete adjuvant, Freund's incomplete adjuvant, Merck Adjuvant 65, aluminum phosphate, alum, quil A, 3D-MPL, QS7, β-escin, digitonin, AS2, ENHANZYN, MPL, QS21, CWS, TDM, AGP, CPG, Leif, saponin, and saponin mimetics.
- 26. (as filed) The composition of claim 1, 4, 7, 15, or 18, further comprising BCG.

Application No.: 09/688,672

Page 9

27. (as filed) The composition of claim 1, 4, 7, 15, or 18, further comprising an NS1 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex.

- 28. (as filed) The composition of claim 1, 4, 7, 15, or 18, wherein the *Mycobacterium* species is *Mycobacterium tuberculosis*.
- 105. (as filed) A fusion protein comprising an MTb81 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, and an Mo2 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex.
- 106. (as filed) The protein of claim 105, wherein the fusion polypeptide has the amino acid sequence of TbF14.
- 107. (as filed) A fusion protein comprising a TbRa3 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, a 38kD antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, a Tb38-1 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, and a FL TbH4 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex.
- 108. (as filed) The protein of claim 107, wherein the fusion polypeptide has the amino acid sequence of TbF15.
- 109. (as filed) A fusion protein comprising an HTCC#1 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis

**PATENT** 

Application No.: 09/688,672

Page 10

complex, and a TbH9 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex.

- 110. (as filed) The protein of claim 109, comprising a full-length HTCC#1 antigen from a *Mycobacterium* species of the tuberculosis complex, and a full-length TbH9 antigen from a *Mycobacterium* species of the tuberculosis complex.
- 111. (as filed) The protein of claim 110, wherein the fusion polypeptide has the amino acid sequence of HTCC#1(FL)-TbH9(FL).
- 112. (as filed) The protein of claim 109, comprising a polypeptide comprising amino acids 184-392 of an HTCC#1 antigen from a *Mycobacterium* species of the tuberculosis complex, a TbH9 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, and a polypeptide comprising amino acids 1-129 of an HTCC#1 antigen from a *Mycobacterium* species of the tuberculosis complex.
- 113. (as filed) The protein of claim 112, wherein the fusion polypeptide has the amino acid sequence of HTCC#1(184-392)/TbH9/HTCC#1(1-129).
- 114. (as filed) A fusion protein comprising a TbRa12 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex, and an HTCC#1 antigen or an immunogenic fragment thereof from a *Mycobacterium* species of the tuberculosis complex.
- 115. (as filed) The protein of claim 114, wherein the fusion polypeptide has the amino acid sequence of TbRa12-HTCC#1.